UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,752	04/16/2001	Jose Halperin	H0498/7137(ERG)	5292

7590 10/21/2002

Edward R. Gates
Wolf, Greenfield & Sacks, P.C.
Federal Reserve Plaza
600 Atlantic Ave
Boston, MA 02210

EXAMINER	
DECLOUX, AMY M	
ART UNIT	PAPER NUMBER
1644	9

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/835,752	Applicant(s) HALPERIN, JOSE	
	Examiner Amy M. DeCloux	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 5-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4 and 9-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/14/01* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group IV, claim 4 in Paper No. 8, filed 8-6-02, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Newly added claims 9-40 also drawn to the elected invention are also under consideration.

2. Claims 1-3 and 5-8 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 4 and 9-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for determining regression, progression or onset of diabetes comprising obtaining a level of the amount of K41-glycated CD59 from urine obtained from a subject and comparing the level to a control as a determination of regression, progression or onset of the condition, using an agent that comprises antibodies that bind glycated and nonglycated CD59, does not reasonably provide enablement for a method for determining regression, progression or onset of ANY condition characterized by abnormal levels of glycated protein comprising obtaining a level of the amount of K41-glycated CD59 from ANY sample obtained from a subject and comparing the level to a control as a determination of regression, progression or onset of the condition, using ANY agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are drawn to for a method for determining regression, progression or onset of a condition characterized by abnormal levels of glycated protein comprising obtaining a level of the amount of K41-glycated CD59 from a sample obtained from a subject and comparing the level to a control as a determination of regression, progression or onset of the condition

The instant specification teaches on page 25 that the K41-H44 of CD59 constitutes a glycosylation site. Page 27 and Figure 5 discloses higher levels of glycated CD59 was detected in the urine of diabetic patients compared to the urine of non-diabetic subjects, by using an antibody specific for the glycated region of CD59 and an antibody that binds both glycated and non glycated CD59. That the levels of glycated CD59 correlate with levels of glycated hemoglobin from diabetic and nondiabetic subjects is also disclosed on Page 27 and Figure 5.

However, the specification does not disclose any condition characterized by abnormal levels of glycated protein, other than diabetes, wherein the levels of glycated CD59 relative to non glycated CD59 correlate with the regression, progression or onset of said condition. Neither does the specifcation disclose that any sample, other than urine, contains higher levels of glycated CD59 in diabetic patients compared to non-diabetic subjects.

The art at the time the invention was made, does not teach a correlation between the levels of glycated CD59 (relative to non glycated CD59 or to a control), and the regression, progression or onset of any condition. Therefore, it would require undue experimentation for one of skill to predict which diseases could be monitored in terms of their regression, progression or onset, other than diabetes, without further guidance from the specification. Further, it would require undue experimentation for one of skill to predict which samples, other than urine, could be used to detect the levels of glycated CD59 in a method for determining regression, progression or onset of a condition characterized by abnormal levels of glycated protein, including wherein said condition is diabetes, without further guidance from the specification.

The specification does not disclose the claimed method wherein the level of CD59 (glycated or nonglycated) is determined by any specific agent other than one comprising antibodies. Therefore, in view of the large number of potential CD59 binding agents, known and unknown , it would require undue experimentation for one of skill to make said agents, other than an agent comprising antibodies, without further guidance form the specification.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the

organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux
Patent Examiner,
October 15, 2002

Patrick J. Nolan, Ph.D.
Primary Patent Examiner
Group 1640